NASA Reference Publication 1392

ISO 9000 Implementation and Assessment

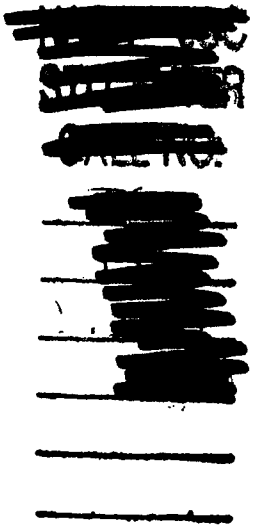
A Guide to Developing and Evaluating Quality Management Systems

Robert J. Navarro and Barry Grimm

September 1996

National Aeronautics and
Space Administration

NASA Reference Publication 1392



ISO 9000 Implementation and Assessment

A Guide to Developing and Evaluating Quality Management Systems

Robert J. Navarro, Ames Research Center, Moffett Field, California
Barry Grimm, Hernandez Engineering, Inc., Moffett Field, California

September 1996

National Aeronautics and
Space Administration

Ames Research Center
Moffett Field, California 94035-1000

PREFACE

The ISO 9000 family of standards defines an excellent foundational quality management system. These standards contain the basic elements of customer focused process measurement, management and improvement that are the hallmark of world class enterprises.

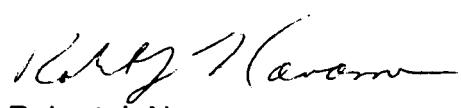
The ISO 9000 standards are simultaneously comprehensive and flexible. Comprehensive, because they define quality in terms of conformance to requirements — customer requirements, safety and reliability requirements, statutory and regulatory requirements. Comprehensive too, because they address quality at all phases of the product life cycle. And flexible, because they specify which management system elements are essential while allowing organizations to meet those requirements in a wide variety of ways that best suit their size, culture and environment.

ISO 9000 provides a well conceived framework that can help any NASA or supplier organization pull together the often disparate elements of its management systems. Applying the standards can be done in many ways — some more valuable than others. NASA's transition to the ISO 9000 standards should be seen as an opportunity to evaluate our processes and upgrade them at the same time we are aligning them with ISO 9000 and documenting them.

The Agency has developed this Guide to aid NASA organizations and their suppliers in this transition. The Guide focuses on the standard's intent, clarifies its requirements, offers implementation examples and highlights interrelated areas. It should prove helpful to anyone developing or evaluating NASA or supplier quality management systems. It is a useful tool to assist enterprises in the application of a powerful management standard.

Carl H. Schneider

Technical Assistant
To the Associate Administrator,
Office of Safety and Mission Assurance



Robert J. Navarro

Chief,
System Safety, Reliability
and Quality Assurance Office

TABLE OF CONTENTS

1 INTRODUCTION

1.1 PURPOSE

This guide was developed to assist NASA organizations and their suppliers in the application of the ISO 9000 family of quality management standards.

1.2 SCOPE

This guide addresses the twenty elements of ISO 9001. From ISO 9004-1, the use of Quality Costs as a measure of management system effectiveness is also addressed. Because ISO 9002 and 9003 contain a subset of the elements of ISO 9001, this guide can also be used to interpret their requirements.

There are several other guidance standards and conformance standards that complete the ISO 9000 family. They deal with the selection, interpretation and application of various aspects of the quality system standards mentioned above. These standards are listed in the Bibliography, along with purchasing information – but they are not specifically discussed in this guide.

1.3 APPLICABILITY

This guide is not intended to be official interpretation. Like other reference texts, it can be used by a NASA or supplier organization during the development and implementation of their quality management system and its quality manual, quality plans, documented procedures and work instructions in accordance with ISO 9000.

These organizations can also use this guide to help assess their supplier's quality systems – to determine if all elements of the ISO 9000 standards are adequately documented and fully implemented.

1.4 DEFINITIONS

The various ISO 9000 standards do not consistently use the same terms to describe each tier of the supply chain. In this guide, the following terms are used:

Enterprise or Organization – used to describe the group that seeks to implement an ISO 9000 quality management system.

Supplier – the enterprise's suppliers.

Customer – the enterprise's customers.

Subsuppliers – the firms used by the enterprise's suppliers.

To avoid acronyms and technical jargon, commonly used terms are employed in this guide when exploring the occasionally cryptic language of the standards.

However, an organization seeking third party registration of their quality system may wish to refer to the official vocabulary in ISO 8402 when interpreting the standards for themselves. The contents of that document are not reprinted here – ordering information is contained in the Bibliography.

1.5 USING THIS GUIDE

GUIDELINES VERSUS REQUIREMENTS

This document contains no requirements – only guidelines. The ISO 9000 family of standards contain the requirements that organizations must understand, interpret and implement.

The ISO 9000 standards have two great strengths:

- They define what elements a management system must address without prescribing how they must be implemented.
- They recognize that the quality management system is a critical element in every enterprise's success in satisfying customer requirements.

For these reasons ISO 9000 is being embraced by an extraordinary range of large and small, government and private sector, service, production and software enterprises that never implemented similar standards like MIL-I-45208, MIL-Q-9858 or NHB 5300.4 (1B).

The standard's unparalleled flexibility allows organizations to systematically manage quality using a wide variety of processes that best fit their specific environment, size and culture. However, the non-prescriptive nature of the ISO 9000 standards may also result in variable interpretation. This guide is intended to assist organization's with interpretation, implementation and assessment.

The interpretations, clarifications and examples used in this guide should never be viewed as requirements. Any difference of opinion that may arise during the development or assessment of a quality management system should be resolved by referring to the requirements of the applicable ISO 9000 standard. And, one should never lose sight of the underlying intent when trying to implement the standard's specific language.

HANDBOOK STRUCTURE

Section 2 of this guide has 21 elements – one for each element of ISO 9001, plus Quality Costs from ISO 9004-1. Each element addresses the following areas:

Intent

The underlying intent of each ISO 9000 element will be briefly discussed.

Benefit

The operational performance benefits from full implementation of each ISO 9000 element will be described.

Interpretation

The requirements of the ISO 9001 element will be summarized, and clarification provided when necessary. Typical methods that might be used to satisfy the requirement will be discussed and relationships with other elements of the standard will be highlighted.

Implementation And Assessment

For each ISO 9001 element, guidance is provided to those developing documented operating procedures, and to those assessing the adequacy of such procedures. These guidelines suggest the who, what, when and how that should be defined in each procedure:

Who: Functional titles will be most useful to the enterprise's own personnel (eg. "The Responsible Project Manager ...").

What: The activity necessary to comply with the standard is described (eg. "... will initiate project quality planning ...").

When: The first step in the process or the required sequence of process steps is identified (eg. "... upon turnover of customer computer codes ...").

How: The specific method is defined (eg. "... using the latest revision of Project Planning Worksheet ABC-999.").

Audit checklists can also be developed from these guidelines to assess the level of operational compliance to the requirements of the standard.

(SECTION 2 FOLLOWS)

2 QUALITY SYSTEM IMPLEMENTATION AND ASSESSMENT

Elements 2.1 through 2.21 of this guide discuss the intent, benefits, interpretation, implementation and assessment of the 20 elements of ISO 9001 plus Quality Costs from ISO 9004-1.

2.1 MANAGEMENT RESPONSIBILITY

Element 4.1 of ISO 9001 defines those parts of a quality system that only management has the authority to implement.

Intent

In order to assure that an enterprise's quality objectives and commitment to quality and customer satisfaction are consistently understood, implemented and maintained at all levels, the standard requires management's active involvement to:

- Establish quality policy.
- Define quality responsibility, authority and interrelationships.
- Provide adequate resources for quality management system implementation.
- Continuously review the effectiveness of the quality management system.

Benefit

Focusing management attention on the development and communication of quality policy, the assignment of specific quality responsibility and authority, and the planning and deployment of resources assures that the organization's quality and customer satisfaction objectives are widely understood and implemented.

Management's regular review of quality system performance assures that all levels of the organization continue to place an appropriate priority on quality improvement and customer satisfaction.

Interpretation

The ISO 9001 standard recognizes that only management has the authority and responsibility to implement several critical elements of the enterprise's quality management system:

1. Executive management must establish a documented quality policy that will:
   - Define management's quality objectives.
   - Define management's commitment to quality.
   - Be relevant to the expectations and needs of the organization's customers.
   - Address the organization's goals.

2. The documented quality policy must be widely communicated so that all levels of the organization understand its intent, and routinely implement it.

3. To minimize organizational gaps and overlaps, and to establish accountability, management must define and document the responsibility, authority and relationship of all personnel who manage, perform or verify work that affects quality.

   This is particularly important in order to preserve the freedom and authority of those personnel who must verify conformance, identify, correct and prevent product and process problems, and control the use of nonconforming product.

4. After establishing its quality policy, and the organizational responsibility and authority for work affecting quality, the enterprise's management must:
   - Determine the type and level of personnel and other resources necessary to adequately implement that policy and responsibility.
   - Make those resources available – including the assignment of adequately trained personnel.

   The enterprise's quality planning process (ISO 9001 element 4.2.3.b) is where these personnel, skill and material resource requirements could be identified and developed.

5. The standard requires an organization's executive management to appoint a "management representative". This person must be a member of the enterprise's management team and may have other duties in addition to those related to the quality system. However:
   - They must have clearly defined responsibility and authority for ensuring that an ISO 9000 compliant quality system is developed, documented, implemented, maintained and improved.
   - They will also be responsible for reporting quality system performance to executive management for its review, with the objective of improving the quality system and quality performance.

This delegated responsibility from executive management may also include liaison with customer, regulatory or third party registrars who conduct assessments of the enterprise's quality management system.

In very small enterprises, there may be no need to appoint a management representative if executive management performs those functions.

6. Executive management must periodically review the performance of its quality system:
   - The review frequency must be defined, and must be sufficiently frequent to assure the continuing effectiveness of the quality management system.
   - These reviews must assess the suitability and effectiveness of the quality system to:
     - Satisfy the requirements of the organization's previously documented quality policy and objectives.
     - Satisfy the requirements of ISO 9001.
   - Data that could form the basis of these quality system reviews might include:
     - Current and overdue corrective action requests arising from:
       - Customer complaints.
       - Internal audit findings.
       - Customer or third party audit findings.
       - Findings from audits of supplier quality systems.
       - Supplier product deficiencies.
     - Field service and field failure data.
     - Trends in nonconformance prevention, detection and correction costs.
     - Status of process improvement teams and other preventive action projects.
     - Process performance metrics, such as first pass yield, cycle time and coefficient of process capability.
   - Written records of quality management system reviews must be generated and maintained in accordance with the standard's Quality Records provisions (ISO 9001, element 4.16).

     Such records might include meeting minutes showing the responsibility and completion schedule for action items resulting from the review.

Implementation And Assessment

Those elements of the quality management system for which only management has the authority and responsibility must be documented. Once adequately documented each element must be fully implemented, as evidenced by direct observation of activities, records, or data.

The quality system procedures that document management's authority and responsibility should:

1. Define how the enterprise's quality policy and objectives will be developed, reviewed and revised.

2. Identify which member of executive management is responsible for assuring development of the enterprise's quality objectives and quality policy.

3. Define how executive management's quality policy and objectives will be communicated to all levels of the organization and who is responsible for their communication.

4. Identify who is responsible for defining and documenting the responsibility, authority and organizational relationship of personnel whose work affects quality, and in what form it will be documented.

5. Define how requirements for the type and quantity of personnel, facility and material resources will be developed in order to adequately implement the enterprise's quality policy and responsibility assignments. The process for definition of training requirements might be addressed in these procedures or in a separate Training procedure in accordance with ISO 9001, element 4.18.

6. Identify who is responsible for developing the above resource requirements, and who is responsible for timely resource deployment.

7. Identify which member of the management team will act as the enterprise's quality system "management representative". Define their responsibility and authority, and to which member of executive management they will report.

8. Define how frequently executive management will review quality system performance and who will participate in these reviews. The types of data to be reviewed might also be identified.

9. Identify which forms and records are required for complete implementation of this portion of the quality management system.

10. Define the methods and responsibilities for initial preparation and filing of records of management reviews. The subsequent accumulation, maintenance and disposition of these records could be defined in the organization's Management Review procedure or in a related procedure for Quality Records (ISO 9001, element 4.16).

(SECTION 2.2 FOLLOWS)

2.2 QUALITY SYSTEM

Element 4.2 of ISO 9001 addresses the overall quality system structure and content needed to deploy executive management's quality policy and management's delegated authority and responsibility for work affecting quality.

Intent

A quality system that defines and documents how key processes are intended to function is the first step toward reducing process variability and increasing product consistency and conformance to customer and internal requirements.

Benefit

A documented quality system improves process and product consistency and reduces the extra labor, material and time needed to correct nonconformities. Cost and schedule performance will improve, and will also become more consistent and predictable. Customers will receive fewer errors and defects and will be more satisfied – so post-delivery complaint costs will also decline.

Interpretation

The standard requires each enterprise to develop, implement and maintain a documented quality management system, whose objective is consistent product conformance to specified requirements.

The enterprise's quality system is defined in:

- Its quality manual.
- Written procedures that define the enterprise's operating processes.
- Quality planning that defines how the specified requirements for particular products, projects or contracts will be addressed:

Quality Manual / Operating Procedures

1. The organization's quality system must be defined in a quality manual.

2. The quality manual must define the types, levels and interrelationships of the documentation that defines the organization's quality system. A "tree" diagram showing how various types of policies, plans, procedures and work instructions relate to one another could be used.

3. The quality manual must either include, or identify by reference, the specific documented operating procedures that define the organization's quality system.

4. The quality manual and the associated operating procedures must address the elements of the ISO 9001 standard and must be consistent with the enterprise's documented quality policy and objectives.

5. The operating procedures may be more or less detailed – based on the complexity of the processes being described and the level of experience and training of the associated personnel. Where required to assure consistent understanding and implementation of key processes, the operating procedures may reference detailed work instructions which need not be part of the quality manual.

6. Sometimes a flow chart, or even a well designed form, may adequately define the who, what, when and how of a process. In this case, the flow chart or form might be referenced in an extremely brief operating procedure. Because such flow charts and forms are effectively the management approved definition of the intended process, they should be numbered and revision controlled.

7. Once the enterprise has addressed all elements of ISO 9001 in its quality manual and documented procedures, the responsibilities, processes and requirements defined in those documents must be effectively implemented.

Quality Planning

1. For each product, project or contract, the enterprise must define and document how it plans to address the applicable requirements.

2. Whether products are developed in response to accepted orders, or are developed in advance of customer demand, the quality planning process should interface with the related process for review of proposal and order requirements addressed in ISO 9001 element 4.3 — Contract Review.

3. The quality planning process should also interface with the design development process addressed in ISO 9001 element 4.4 — Design Control. Ideally, quality planning and design development are concurrent and interactive. Quality Function Deployment (QFD) is a useful tool to allow all affected groups to simultaneously identify, correlate and balance key customer requirements, design features and process control elements.

4. Because some enterprises may have fully integrated requirements review, design development and quality planning processes the standard provides great flexibility regarding how quality planning must occur and be documented. The standard requires a documented quality planning activity, but does not require the creation of discrete quality plans, per se. The standard only requires that the enterprise consider the need for preparation of discrete quality plans.

   Regardless of how the organization conducts its quality planning effort, the following items must be considered:

- Identification of necessary resources, including the need for development or acquisition of:
  - New or improved process or process control technology.
  - New or modified equipment, tools or facilities to produce, inspect, test, install or service the product.
  - Additional personnel resources or upgraded skills.
- Identification of any needed measurement capability that may exceed current state of the art — so that adequate capability can be developed in a timely fashion.
- Identification of new or revised written procedures or work instructions to support the design, creation, process control, inspection, test, installation or servicing of the anticipated product.
- Identification of appropriate verification points in the design, development, procurement, production, installation and servicing processes; and definition of the required types of verification at each point.
- Definition of objective or subjective acceptance standards for all requirements.
- Identification of the type, frequency and point of generation of all necessary quality records.

5. At its simplest, a quality plan might only need to identify by reference which elements of the enterprise's quality manual, written procedures and work instructions will apply to the specific product, project or contract in question.

Implementation And Assessment

Each enterprise's quality management system must be documented. Once adequately documented each element of the quality system must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documentation that defines the organization's quality system should:

1. Identify who is responsible for the development, implementation and maintenance of the enterprise's quality manual, if not already specifically defined in the organization's written procedure for Management Responsibility (ISO 9001, element 4.1).

2. Define how the quality manual and the associated operating procedures and work instructions will be reviewed and approved, and how their appropriate distribution will be established. This key process could be addressed in the organization's Quality System procedure or in the related procedure for Document and Data Control (ISO 9001, element 4.5).

3. Identify who is responsible for coordination of the enterprise's quality planning effort.

4. Define how the quality planning process is intended to function. Define under what circumstances a discrete quality plan would be developed for specific products, projects or contracts and who is responsible for making that determination.

   The organizational and chronological relationship between the quality planning process and the enterprise's requirements review and design development processes (ISO 9001, elements 4.3 and 4.4) should be defined.

5. Define how quality planning documentation will be reviewed and approved, and how the appropriate distribution will be established. This could be addressed in the organization's Quality System procedure or in the related procedure for Document and Data Control (ISO 9001, element 4.5).

6. Identify which forms and records are required for complete implementation of this portion of the quality management system.

(SECTION 2.3 FOLLOWS)

2.3 CONTRACT REVIEW

Element 4.3 of ISO 9001 specifies the necessary elements in an enterprise's process for establishing / reviewing requirements in outgoing proposals and incoming orders.

Intent

When undertaking new projects, contracts or product development activities, a systematic requirements development and review process will result in requirements which are comprehensive, clearly understood, adequately documented and fully communicated to all affected groups at the earliest stage of activity.

Benefit

Unanticipated requirements result in unplanned costs, adverse schedule impacts, requests for concessions and customer dissatisfaction. The later these unexpected requirements appear, the larger the adverse impacts. These unforeseen requirements are much less likely when the needs of all concerned groups are solicited in a structured manner, fully documented and communicated, understood and reconciled as early in the product development cycle as possible.

Interpretation

The standard requires each enterprise to establish and maintain documented procedures defining their requirements review process:

1. The process must assure that all applicable requirements are clearly defined, documented and communicated:
   - Prior to submission of a proposal.
   - Before order acceptance.

   Such requirements might include product performance, safety, reliability, statutory, regulatory and other internal and customer requirements.

2. The process must define how any unwritten requirements that are received will be reviewed before acceptance.

3. The review process must provide for:
   - Identification and resolution of differences between the requirements in the proposal and those in the subsequent order.
   - Identification and resolution of unclear or conflicting requirements.
   - Resolution of any disparity between requirements and the organization's capability to meet those requirements.

4. Menu-style requirements checklists are one way to assure that the requirements of customers and all affected groups are consistently identified and documented.

5. How the output from the contract review process will affect the quality planning process (ISO 9001, element 4.2.3) and the design and development planning process (ISO 9001, element 4.4.2) could also be defined.

6. A written record of requirements reviews must be generated and maintained in accordance with the standard's Quality Records provisions (ISO 9001, element 4.16). Such records might include:

   - The requirements checklists discussed above.
   - Requirements review meeting minutes showing action items to resolve unclear, conflicting or unachievable requirements.

   The above requirements checklists could also serve as:

   - The basis for subsequent design review agendas where design outputs must be verified as conforming to all design input requirements.
   - The record of those design review meetings — in accordance with ISO 9001, elements 4.4.6 and 4.16.

7. The process for reviewing, communicating and implementing modifications to the requirements in proposals or orders must also be documented.

Implementation And Assessment

Documented procedures for the development and review of proposal and order requirements must define the who, what, when and how of the process. Once adequately documented each element of the procedure must be fully implemented, as evidenced by direct observation of activities, records, or data.

Requirements review procedures should:

1. Define the methods and forms to be used to:

   - Develop and review proposal requirements before submission.
   - Receive, document and review incoming order requirements – both written and verbal.

2. Identify who will be responsible for assuring that proposal and incoming order requirements are clearly defined and adequately documented.

3. Identify which functions must contribute to the definition of proposal requirements, and must review the requirements of incoming orders. Also define who is responsible for coordinating such cross-functional requirements development and review.

4. Define how conflicting requirements will be highlighted and resolved, and identify who is responsible for resolution.

5. Identify how any differences between requirements and the organization's capability to meet those requirements will be identified and resolved, and who is responsible for resolution.

6. Identify how accepted order requirements will be communicated to all affected functions.

7. Identify the interface between the contract review process, the quality planning process and the design and development planning process.

8. Define how revisions to requirements will be received, documented, reviewed, reconciled and communicated to all affected groups.

9. Identify which forms and records are required for complete implementation of this portion of the quality management system.

10. Define the methods and responsibilities for initial preparation and filing of records of requirements reviews. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Contract Review procedures or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.4 FOLLOWS)

2.4 DESIGN CONTROL

Element 4.4 of ISO 9001 defines the major elements that each enterprise's design and development process must address.

Intent

Systematically designing and documenting the process for design, clearly defining all organizational interfaces, and actively planning the development of each new product design will assure that the organization consistently meets all customer and internal requirements.

Benefit

Designs that do not fully meet internal and regulatory requirements and user needs require unplanned design modifications that result in adverse cost and schedule impacts and customer dissatisfaction. Design modifications will have a tolerable impact if made before substantial design effort begins. Impact will be much greater if changes are made to completed designs, and the cost and customer impact can be extreme for design changes made after product has been created, delivered or deployed.

However, the frequency and magnitude of such problems can be substantially reduced when:

- All necessary steps in the design and development process are clearly defined and documented.
- The requirements of all stakeholders, and the design-related responsibilities of all affected groups, are systematically defined and planned before significant design effort begins.
- Design outputs are reviewed by all affected groups, and verified as meeting their design input requirements.
- Completed designs are operationally validated as meeting user needs.
- Design changes are systematically managed.

Interpretation

The standard requires each enterprise to establish and maintain documented operating procedures defining how the design of their products and services will be developed, controlled and verified as meeting requirements:

1. For each design and development project, documented plans must define the necessary design activities and the associated responsibility for their implemen-

tation. The design and development plan must be reviewed and updated as required during the evolution of the design.

2. The organizational and technical interfaces between all groups concerned with the design and development effort must be defined. Concerned groups that are often outside the design group include Reliability Engineering, Quality Engineering, System Safety Engineering, Maintainability Engineering, Producability Engineering and Regulatory Compliance.

   Design and development planning, quality planning (ISO 9001 element 4.2.3) and the review of proposal and order requirements (ISO 9001 element 4.3) can be concurrent and interactive. Tools like Quality Function Deployment (QFD) might be used to identify, correlate and balance key customer requirements, design features and necessary control elements in design, production and verification processes. These interfaces could be documented in the required design and development plan discussed above.

3. Design activities must be carried out by qualified personnel, equipped with adequate materials, facilities and support.

4. The methods and responsibilities for identifying design requirements must be defined. These requirements might include customer requirements, reliability, maintainability and operational safety requirements, performance requirements, producability and inspectability requirements and statutory or regulatory requirements.

5. The above design inputs must be documented and reviewed for adequacy and completeness. For any conflicting, unclear or incomplete design requirements, the group that originally imposed the requirements must be involved in their resolution. Menu-style checklists are one way to identify, document, review and record the resolution of each group's design requirements.

6. The product design that is the output of the design and development process must:

   - Be documented. Typical design documentation might include product drawings, specifications, software, operating and servicing instructions.
   - Satisfy the design input requirements.
   - Include design call-outs that address the safe and proper functioning of the product. These might include the definition of applicable operating instructions, handling, packaging and storage specifications and installation, maintenance and disposal requirements.
   - Define the acceptance criteria for each design characteristic, either by inclusion in the design documentation or by reference.
   - Be expressed in terms that can be verified as meeting design input requirements.

     For instance, a design call-out for "surface cleaning per X-999 process specification" is a verifiable way to implement a difficult to verify design input requirement like "free of surface contaminants".

- Be expressed in terms that can be validated as meeting user needs.

  For example, a user expectation that there be "no sharp edges" is impossible to confirm unless specified as "break all edges to .XX minimum radius."

7. Documents that define the completed design must be reviewed before release.

8. At appropriate stages of the design and development process, the design must be verified as conforming to design input requirements during formal design reviews:

   - Design review meetings must include representatives from all groups concerned with the design stage being reviewed.
   - The definition of when design reviews will be conducted, and what other design verification methods are to be used must be documented in the design and development plan discussed above.

     In addition to design reviews, verification of conformance to design input requirements might include tests, inspections, demonstrations, independent engineering analyses and calculations, and comparison of design elements to similar elements of proven designs.
   - Suitable records of all design reviews, and records of any other design verification activities, must be made and maintained in accordance with the Quality Records provisions of ISO 9001, element 4.16.

     Design review records might include meeting minutes showing design review action items. Log books and computer files of engineering analyses, and completed test reports would be typical examples of other verification records.

9. Designs must also be validated as meeting user needs:

   - Validation is typically performed under defined operating conditions.
   - Validation usually follows the successful verification that the design meets all previously defined design input requirements.
   - Validation is usually performed on the completed product, but may also be performed at intermediate design stages or on important sub-systems.
   - Multiple validations may be needed to confirm that the design meets user needs in each anticipated application or environment.

10. Design changes must be documented, and reviewed and approved by authorized personnel before implementation.

    In schedule-critical circumstances, quick-change processes with less formal documentation and fewer reviews may be appropriate. However, such abbreviated change processes must be documented and individual design changes still must be documented and authorized before implementation.

Implementation And Assessment

The enterprise's process for developing, verifying and controlling the design of products and services must be documented. Once adequately documented each element of the procedure must be fully implemented, as evidenced by direct observation of activities, records, or data.

Design and development procedures should:

1. Define who is responsible for preparation of the plan for each design and development activity and define at what stage of development the plan must be prepared.

2. Define who must review and approve the plan, and under what conditions such plans should be revised.

3. Specify the process for identifying design input requirements, including how requirements will be documented and who is responsible for coordination of the process. Reference could be made to the related procedures for Contract Review (ISO 9001, Element 4.3) and Quality Planning (ISO 9001, Element 4.2.3).

4. Define how design output (e.g.. drawings, specifications, etc.) will be documented, reviewed, and released. Reference could be made to the related procedure for Document and Data Control (ISO 9001, Element 4.5).

5. Define how and when design reviews will be conducted, who is responsible for conducting the reviews and which groups must be considered for inclusion.

6. Define how the need for other design verification activities (e.g. tests and analyses) will be established, and identify responsibilities for developing and conducting these verification activities.

7. Define the methods and responsibility for initial preparation, filing, and tracking of design review records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Design Control procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

8. Define how validation activities to confirm that user needs are met will be established, and identify responsibilities for developing, documenting and conducting the validation activities.

9. Define the process for documenting, reviewing and approving design changes, including methods and responsibilities.

10. Identify which forms and records are required for complete implementation of this portion of the quality management system.

(SECTION 2.5 FOLLOWS)

2.5 DOCUMENT AND DATA CONTROL

Element 4.5 of ISO 9001 defines the requirements for controlling documents and data associated with the operation of the enterprise's quality management system.

Intent

Systematic management of the creation, release, distribution and modification of documents that affect quality will assure that the contents are adequate, and that the correct revisions of all necessary documents are available at every location where they are needed to correctly perform the work.

Benefit

Fewer errors and omission and their adverse impacts to cost and schedule will occur when only fully adequate and authorized documents and revisions are used by all personnel whose work affects quality.

Interpretation

ISO 9001 requires each enterprise to establish and maintain written procedures defining their process for controlling all documents and data used in work affecting quality:

1. Documents and data which are required for the operation of the enterprise's quality system must be controlled. These controlled documents could be in any form, such as hard copy, electronic media or microfiche, and should include:
   - The organization's quality policy and quality manual.
   - Procedures (eg. Drawing Release, Supplier Qualification, Design Verification).
   - Inspection and test plans, procedures and instructions.
   - Work instructions and key business forms.
   - Process descriptions and flow charts.
   - Audit plans, design development plans and project quality plans.
   - Internal, customer and supplier product drawings.
   - Internal, National, International and customer specifications or standards.
   - Installation, operation and servicing manuals.
   - Reports and other records whose use affects current operations.

- Process / product evaluation or control software.
- Customer deliverable documents.
- The master document control list that defines the release and revision status of all other controlled documents.

Other customer and supplier documents and data might also require control to the extent that their use affects the quality of the enterprise's products and services.

2. Before release for use, controlled documents must be reviewed for completeness and adequacy, and approved by authorized personnel.

3. Revised documents must be reviewed by the same functions that approved the originals unless alternate review and approval requirements are clearly defined:
   - Reviewers must have access to any related information that supports the document's revision, and that may be helpful in their review.
   - To the extent practical, the nature of the revisions should be identified in the documents or its attachments.

4. All necessary documents must be made available at each location where work affecting quality is performed. Availability in the general area of grouped workstations may be adequate to support operations. Delivery of hard copy, or on-line availability via computer networks are both acceptable.

5. To preclude the unintended use of un-released drafts, or obsolete documents, a master document control list showing each document's currently authorized revision level must be continually updated and maintained and must be made readily available to document users.

6. Obsolete documents must be promptly removed from all points of use. Suitable methods could include physical retrieval of obsolete hard copy, or posting replacement documents to computer networks with a notification of availability to network users.

7. Any obsolete documents that are retained for legal or knowledge preservation purposes must be clearly identified. Use of a red "OBSOLETE" ink stamp on each document is one way to satisfy this requirement.

Implementation And Assessment

The organization's process for controlling documents and data that affect quality must be defined in writing. Once adequately documented each element of the procedure must be fully implemented, as evidenced by direct observation of activities, records, or data.

Such document control procedures should:

1. Define which types of documents and data will be controlled. In the procedure, reference can be made to product quality plans (ISO 9001, element 4.2.3) for any document control requirements that are unique to specific projects or contracts.

2. Identify who is responsible for interpreting the criteria for which documents must be controlled.

3. Identify who is authorized to review and approve each type of document prior to its initial release or revision. Also define how changes will be documented and how approval will be recorded.

4. Define how the current revision status of controlled documents will be documented and how that information will be communicated to personnel using the controlled documents. Also define who is responsible.

5. Identify how the correct distribution of each document type will be determined. Also define how document release and distribution will be made, and who is responsible.

6. Specify how obsolete documents will be collected (or otherwise assured against unintended use), including who is responsible.

7. Define how obsolete documents that are retained for future reference will be clearly identified and who is responsible for their identification and maintenance.

8. Identify which forms and records are required for complete implementation of this portion of the quality management system.

9. Define the methods and responsibility for preparation and filing of any document control records that will be managed in accordance with the quality records provisions of ISO 9001, element 4.16. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Document and Data Control procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.6 FOLLOWS)

2.6 PURCHASING

Element 4.6 of ISO 9001 defines the quality related requirements for each enterprise's procurement processes.

Intent

Using supplier selection criteria, that includes the adequacy of their quality management system and their past performance, will maximize the probability of the supplier meeting the purchaser's requirements.

Systematically establishing procurement requirements that are comprehensive and clear will assure that suppliers better understand all purchaser expectations.

Benefit

When suppliers are selected based on tangible evidence of their ability to meet customer requirements, the frequency of supplier deficiencies and the resulting unplanned costs and adverse schedule impacts will be greatly reduced.

If purchase requirements are solicited in a systematic way and are clearly documented and communicated to the supplier, omissions, misunderstandings and the costs and schedule delays of return and replacement will be minimized.

Interpretation

The ISO 9001 standard requires that each enterprise establish and maintain documented procedures defining their processes for selecting suppliers and specifying purchase requirements:

1. Suppliers must be evaluated and selected based on their ability to meet the enterprise's procurement requirements. Quality related evaluations might include:
   - Review of the supplier's Quality Manual using ISO 9001 and this guide.
   - On-site assessment of the supplier's operational compliance with their own Quality Manual and documented operating procedures. Audit checklists based on ISO 9001 and this guide could be used to evaluate the adequacy of the supplier's quality management system.

     The purchaser could perform these quality system audits, or review the audit reports of other enterprises that use the same supplier, or accept the supplier's ISO 9000 registration by an accredited third party assessor.
   - On-site assessment of the capability of the supplier's facilities, processes, equipment and personnel to meet applicable technical standards and product requirements.

- Review of the supplier's performance record on previous, similar orders. Such records could include the receiving inspection results for prior deliveries, reports of previous supplier audits, surveys of purchase requester satisfaction, records showing adequate and timely closure of requested corrective actions and reports of problems encountered in the field.

2. Based on evaluations, such as the above, the enterprise must maintain records of acceptable suppliers. For convenience, such records could list all approved suppliers by commodity type and might also rank suppliers based on defined criteria. This ranking could be used as the basis for prescribing more or less control on future orders (see paragraph 3 below).

3. The extent of the controls to be applied to each procurement must be defined. These controls could include activities required of the supplier and activities performed internally. Such controls might include:

   - Purchaser's approval of quality-critical supplier procedures, process equipment, process parameters or personnel certifications.
   - Purchaser's approval of supplier's product qualification plan and/or qualification results.
   - Liaison personnel assigned to the supplier's facility during critical activities.
   - Periodic surveillance audits of the supplier's quality system and quality-critical processes.
   - Release of supplier's production activity following approval of the first article produced.
   - Sampling or 100% source inspection.
   - Sampling or 100% receiving inspection.
   - Review of supplier submitted inspection and test data or process control charts.
   - Oversight testing, performed by the purchaser or by a third party lab.

   The type and extent of control must be based on the type of product or service being acquired, the impact of the procured items on final product or service quality, the supplier's performance record and the assessed effectiveness of the supplier's quality management system.

4. Those purchaser imposed controls that will directly affect the supplier's operations must be defined in the procurement documentation that will be sent to the supplier (see paragraph 3 above).

5. Procurement documents must clearly describe the product or service being ordered including name, type, grade, model number, etc. For specifications, drawings, standards, inspection or test instructions and other applicable documents, the title, number, revision, date or other identifiers must be defined in procurement documents.

6. The number, title and revision of any quality management system standard to be implemented by the supplier must be defined.

7. If the enterprise plans to verify an order's conformance at its supplier's facility, specific methods for verification and subsequent release for delivery must be defined in procurement documents. If the enterprise's customer reserves the right to verify the conformance of sub-contracted product at the facility of the enterprise's supplier, such arrangements must also be defined in procurement documents.

8. Before transmittal to the supplier, the enterprise must review and approve its purchasing documentation to assure that the specified requirements are appropriate, adequate and complete.

   A menu-style checklist could be used to assure that appropriate procurement requirements are consistently selected, documented and reviewed. The checklist could also communicate those requirements to the enterprise's purchasing function, and to the supplier, as an attachment to the purchase order. The checklist might also become the receiving function's inspection plan for order acceptance, and serve as the archivable record of conformance.

9. The enterprise's customer might, by contract, reserve the right to verify conformance of subcontracted work before its delivery. Such verification could occur at the enterprise's facility or at the facility of the enterprise's supplier. The verification could be done by customer personnel or by their duly appointed representatives.

   Despite such pre-delivery customer verification:

   - The enterprise must not treat their customer's successful product verification as evidence of adequate control of quality by the enterprise's supplier.
   - The ISO 9001 standard requires the enterprise to be ultimately responsible for the product's conformance to requirements, including any subsequent rejection by the enterprise's customer.

Implementation And Assessment

The process for supplier selection and the process for generation, review and release of procurement requirements must be defined in writing. Once documented each element of the procedure must be fully implemented, as evidenced by direct observation of activities, records, or data.

Such procedures should:

1. Identify the criteria to be used for qualification of suppliers, including the standard their quality management system must meet.

2. Identify who will evaluate suppliers to determine their initial capability, and how the assessment will be conducted.

3. Define how action items resulting from audits will be addressed and closed with the supplier. Reference could be made to the related procedure on Corrective and Preventive Action (ISO 9001, element 4.14).

4. Identify how ongoing supplier performance will be evaluated, and who is responsible.

5. Define how lists of acceptable suppliers will be documented and communicated to concerned organizations. Define how frequently this information will be updated and who is responsible for its maintenance and distribution.

6. Identify whether there are any circumstances under which previously qualified suppliers need not be used.

7. Define each acquisition process that can have a significant effect on quality. These processes might include contracts and purchase orders, or even credit card or petty cash procurements. For each acquisition method:
   - Identify any purchase request / order forms or other documentation to be utilized.
   - Identify the method for developing, documenting and communicating quality requirements to suppliers and to the organization's receiving function. Reference could be made to the related procedure for Receiving Inspection.
   - Define who must review and approve such acquisition requirements. If some acquisitions do not require a review for procurement quality requirements identify who has the authority to make that determination.

8. Define acceptable sources for documents that must be included or referenced in the procurement documentation package. Reference could be made to the related procedure on Document Control.

9. Identify which forms and records are required for complete implementation of this portion of the quality management system.

10. Define the method and responsibility for the initial filing and tracking of active supplier selection and procurement records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Purchasing procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.7 FOLLOWS)

2.7 CONTROL OF CUSTOMER SUPPLIED PRODUCT

Element 4.7 of ISO 9001 defines the requirements for the management of customer furnished articles.

Intent

The systematic management of customer supplied property will assure that such articles are functional and available for use at the necessary time.

Benefit

When the receipt, verification, storage, maintenance and use of customer supplied articles is effectively controlled, deterioration and loss will be minimized. The extra costs, delays and customer dissatisfaction caused by repair or replacement of such property will be substantially reduced.

Interpretation

Each organization must establish and maintain documented procedures defining how customer supplied property will be controlled, including the following elements:

1. Customer furnished articles must be verified as conforming to requirements at the time of receipt. Review of customer provided records and performance of tests or inspections could be undertaken.

2. Despite such verification of conformance by an enterprise, the ISO 9001 standard requires the customer to be ultimately responsible for the acceptability of the product they are providing.

3. The enterprise must assure that customer supplied articles are appropriately identified, stored and maintained in order to preclude loss, damage or deterioration.

4. Customer property that is lost, damaged or found unsuitable for use must be recorded, in accordance with ISO 9001 element 4.16, and promptly reported to the customer.

Implementation And Assessment

The enterprise's process for controlling customer furnished product must be defined in writing. Once adequately documented each element of the procedure must be fully implemented, as evidenced by direct observation of activities, records, or data.

Such documented procedures should:

1. Define how incoming customer property will be verified as conforming to requirements. Define who is responsible for verification and how receipt and acceptance will be documented. Reference could be made to the enterprise's Receiving Inspection procedure (ISO 9001, element 4.10.2), as appropriate.

2. Define the methods and responsibilities for identification, use, storage, and maintenance of customer furnished property. Reference could be made to the enterprise's Handling, Packaging, Preservation and Storage procedure (ISO 9001, element 4.15), as appropriate.

3. Identify how lost, damaged, or unsuitable customer furnished articles will be recorded, and how the customer will be notified. Also identify who is responsible for such records and notification.

4. Identify which forms and records are required for complete implementation of this portion of the quality management system.

5. Define methods and responsibilities for the initial preparation, filing, and tracking of records relating to customer furnished property. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Customer Property procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.8 FOLLOWS)

2.8 PRODUCT IDENTIFICATION AND TRACEABILITY

Element 4.8 of ISO 9001 defines the requirements for product identification and for unit or batch traceability.

Intent

Systematic identification of products with their part or model number significantly reduces the probability of mix-ups and inappropriate use.

Additionally, identifying individual units or batches with serial numbers or lot numbers facilitates failure analysis for root cause, permits separation of suspect product from other product of the same part or model number, and permits targeted customer notification or recall.

Benefit

Clear identification of products makes efficient stocking and issuance practices possible. It also substantially reduces inadvertent use of similar but incorrect items and the schedule, cost and customer satisfaction impacts of correcting such errors.

Unit or lot traceability permits the cost effective identification, recall and replacement of only those specific units or batches that may be identified as nonconforming or failure prone. Without such traceability, the cost of repair or replacement of all inventory may unduly influence the decision to use marginal product.

Batches or units with a traceable processing history make material and process related failure analysis possible. It also makes systematic process improvement easier when the cause and effect relationship between process and product can be identified.

Interpretation

The standard requires each enterprise to determine whether documented procedures for identification and traceability of product are appropriate for their situation:

1. When appropriate, the organization must identify products by suitable means during receipt, processing, delivery, installation and servicing:
   - Drawing numbers, or the manufacturer's part or model number are frequently used. Sometimes they are expressed as universal product (bar) codes.
   - Suitable identification methods might include indelible ink stamping, tagging, adhesive labels, chemical etching or mechanical engraving.
   - Product identification contained only in accompanying documents, such as process travelers or packing slips, might be acceptable if usage and storage

environments reduce the risk of commingling the documentation between similar products.

2. When specified by customers or regulatory requirements, or due to internal needs, each enterprise will establish, maintain and record the unique batch or unit identity of products:
   - Serial numbers and lot numbers are typically used.
   - Operations logs, work station bar code readers, processing travelers or other suitable records could be used to make the product's location or processing history traceable.

Implementation And Assessment

Where appropriate, the enterprise's methods for product identification and traceability must be defined in writing. Once adequately documented each element of the procedure must be fully implemented, as evidenced by direct observation of activities, records, or data.

These documented procedures for identification and traceability should:

1. Define which products must be identified during receipt, production, delivery or installation.

2. Define which products must also be traceable to their individual unit or batch identity.

3. Define the identification and traceability methods to be used for each product, how those approved methods will be communicated, and who is responsible for their definition and communication.

4. Define who is responsible for initially identifying product and who is responsible for maintaining that identity or traceability at each stage of processing.

5. Identify which forms and records are required for complete implementation of this portion of the quality management system.

6. Define the method and responsibility for initial filing and tracking of records indicating the product's unit or batch traceability. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Product Identification and Traceability procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.9 FOLLOWS)

2.9 PROCESS CONTROL

Element 4.9 of ISO 9001 defines the requirements for the control of production, installation and servicing processes that affect quality.

Intent

The systematic planning and active management of processes that affect quality will reduce unintended process variability which will result in products and services that more consistently satisfy requirements.

Benefit

When process variability is systematically controlled, products and services will more frequently meet requirements. Scrap, unbudgeted rework and associated schedule delays will be reduced, as will unplanned overtime and premium transportation to minimize such delays.

Controlled processes produce higher levels of first time conformance to requirements, so less inspection and fewer audit hours may also be justifiable. And with fewer errors and defects, fewer will slip through inspection and create customer dissatisfaction.

Interpretation

The standard requires each enterprise to:

1. Identify and plan those processes that directly affect the quality of their products and services. These might include production, inspection, installation and servicing processes. Such processes must be conducted under controlled conditions, including the following:

   - Only suitable equipment, facilities and operating environments must be used. Ideally, process performance has been quantified and found to be capable of consistently meeting all requirements when operated in a controlled manner. Graphical process capability studies can be performed to verify that the process is inherently capable of meeting requirements.

     Some truly state of the art processes may not be capable of consistently meeting all requirements, even when operated in a fully controlled manner. However, as the best available, these processes may still be considered suitable.

     Processes that are inherently capable of meeting requirements often fail to do so because of 1.) inadequate frequency and types of controls, 2.) intuitive,

rather than statistically sound process monitoring and adjustment and 3.) physical deterioration due to inadequate maintenance.

- When appropriate, process equipment and operating parameters should be approved by authorized personnel before release for use. Completion of the process capability study discussed above could serve as the basis for authorization of process start-up.
- The intended manner of process operation must be documented. Written procedures, work instructions or flow charts may be used to define the "who, what, how and when" for each process step.

  The process description might also reference the forms, equipment, visual standards, measurement devices, process parameters and any other documents required to implement the process.
- Personnel must be familiar, and comply with, the documented procedures, standards and plans:
  - Any necessary training in the requirements of applicable procedures could be defined in the process documentation, or in the enterprise's related Training procedure (ISO 9001, element 4.18).
  - The responsibility for use of the controlled procedures, standards and plans that define process operation could be specified in the process documentation or as specified in the enterprise's Quality System Requirements procedures (ISO 9001, element 4.1.2.1).
  - Compliance with documented procedures could be monitored by the enterprise's internal audit program in accordance with ISO 9001, element 4.17. Regularly scheduled internal audits will uncover the need for revised procedures or for additional training so that practices match procedures.
- Appropriate process parameters and product characteristics must be monitored and controlled:
  - The parameters and characteristics to be monitored could be identified in documented process procedures and work instructions. These procedures and work instructions might include documentation, video tapes or representative product samples.
  - Gauges and instruments that are used for monitoring process parameters and product characteristics must be controlled in accordance with ISO 9001, element 4.11.
  - Simple histograms and run charts, or more sophisticated statistical process control charts, could be used to record process and product data for use in adjusting process operation. These statistical techniques must be used in accordance with ISO 9001, element 4.20.
- Clear workmanship standards for product acceptability and process operation must be defined, documented and implemented. These standards could include written descriptions, photos or illustrations and physical samples.

- Suitable process maintenance must be provided to preserve or improve the original process capability. This might include preventive maintenance for gauges and instruments used in production and inspection processes. Documented maintenance plans and schedules, and maintenance completion logs or tags could be used.

2. For special processes, where examination of the product to verify conformance to requirements is impractical, the process must be carried out using one or both of the following control techniques:

   - The process must be carried out using pre-qualified equipment, process parameters and personnel whose capability to consistently meet specified process and product requirements has been evaluated.

     Records of the results of such equipment, process parameter and personnel qualifications must be maintained. These records must be managed in accordance with ISO 9001, element 4.16.

   - The process must be continuously monitored and controlled. To be considered "continuous", process monitoring and control should be done with sufficient frequency to detect and correct unintended process changes before nonconforming product is created.

Implementation And Assessment

The organization's procedures for operating quality-critical processes under controlled conditions must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Identify all processes that directly affect quality.

2. Define how the intended method of operation of each process will be planned and documented, and which function is responsible.

3. Identify how process operation and control requirements will be communicated to the functions responsible for process operation.

4. Define, for each process, the methods to be followed in performing the operations under controlled conditions, including:

   - Identification of the plans, procedures, work instructions, acceptance and workmanship standards to be used.

   - Definition of any pre-use qualification requirements for equipment, process parameters or personnel, including who is authorized to approve implementation.

- Identification of required facilities, equipment, tooling, gauges, instruments or working environments.
- Identification of the process parameters and product characteristics that must be controlled, including frequency and method of monitoring, acceptable operating limits and remedial actions when limits are exceeded.
- Definition of the methods to be used to indicate successful completion of the required process steps.
- Definition of the type and frequency of any necessary equipment or facility maintenance.

5. Identify who has the authority to modify process control requirements.

6. Define which equipment, process parameter or personnel qualification records must be generated.

7. Identify which forms and records are required for complete implementation of this portion of the quality management system.

8. Define the method and responsibility for initial filing and tracking of process control records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Process Control procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.10 FOLLOWS)

2.10 INSPECTION AND TESTING

Element 4.10 of ISO 9001 defines the requirements for conducting inspections and tests to verify that specified product requirements have been met.

Intent

Systematically planning appropriate inspections and tests and performing them in a controlled manner will assure that products and services, once accepted, do in fact meet specified requirements.

Benefit

Poorly planned and conducted tests and inspections can result in costly delays and customer dissatisfaction if nonconforming product goes undetected. Adequately planned and controlled inspections and tests will minimize this problem.

Adequately documented test and inspection results provide enterprises and their customers with permanent evidence that products and services meet all specified requirements and will be suitable for use.

Interpretation

To accurately assess whether or not specified requirements have been met, each enterprise must establish and maintain documented procedures defining which inspections and tests are to be conducted, how they are to be conducted, and what records must be generated:

1. For each product, project or contract, the Quality Plan (ISO 9001, element 4.2.3) may be used to identify which inspections and tests are required and what records are to be created. Otherwise this information must be contained in the applicable documented inspection and test procedures.

2. Incoming products must be verified as conforming to specified requirements before they are released for use. Requirements checklists could be completed as part of the purchase request process and transmitted to the supplier and the receiving function. When properly formatted, the requirements checklist can serve as the receiving inspection plan and the required quality record for that procurement.

3. The extent and nature of receiving inspections must be based on the type of product and its intended application, the degree of control exercised by the purchaser and supplier at the supplier's facility and the availability of supplier furnished process control charts, test and inspection results.

The extent of receiving inspection called for could also be tied to the supplier's performance history as reflected in the supplier's ranking in the enterprise's list of approved suppliers (ISO 9001, element 4.6.2).

4. In-process tests and inspections must also be conducted in accordance with planned and documented procedures. These tests and inspections might include random product "audits" by roving inspectors, product measurement or Go/No Go checks made by process operators, set-up or first article inspection, automated inspection stations between specified processing steps.

5. Incoming and in-process products that are released for urgent use before verification of conformance is complete must be positively identified (e.g.. ink stamping, tagging). A record of their incomplete verification must also be made to facilitate subsequent recall and completion of all prescribed inspections and tests.

   Such records of premature release must be treated as Quality Records in accordance with ISO 9001, element 4.16. These records might include annotated inspection logs and annotated processing travelers.

6. Final inspections and tests must be conducted in accordance with planned and documented procedures. Finished product must not be released until:

   - All specified processing has been completed.
   - All required incoming, in-process and final inspections and tests have been completed and conformance to specified requirements has been verified.
   - All required data or documentation must also be available and must be approved by authorized personnel before final product release.

   A standardized checklist could be used to assure consistent final release practices.

7. All product that has been verified as not conforming to specified requirements must be treated in accordance with ISO 9001, element 4.13 — Control of Nonconforming Product.

8. For incoming, in-process and final inspections and tests, records must be maintained. These records must:

   - Provide evidence of inspection and test completion.
   - Document the resulting pass/fail status relative to defined acceptance criteria.
   - Identify the authorized individual or function that accepted or released the product based on the inspection or test results.
   - Be treated as Quality Records in accordance with ISO 9001, element 4.16.

   Properly designed inspection logs, process travelers and test or inspection reports might be used to satisfy this records requirement.

Implementation And Assessment

The enterprise's quality plans and documented procedures must define how inspection and test activities will be developed and implemented. Once adequately documented each element of these plans and procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The quality plans and documented procedures should:

1. Define which receiving, in-process, and final inspections and tests are required, and identify what type of records must be generated.

2. Define how specific inspection and testing requirements will be documented and communicated to affected groups, and who is responsible for their development and transmittal.

3. Define the review and approval requirements for inspection and test procedures. This could be done in the enterprise's Inspection and Testing procedure or in the related procedure for Document Control.

4. Define how receiving and in-process inspections and tests will be conducted in order to assure that products are not released for processing until conformance to all specified requirements has been verified.

5. Define how any articles that must be released for urgent use will be identified and recorded to allow recall for completion of incomplete inspections and tests.

6. Define how the accept / reject status of product will be documented and identify who has the authority to release product following successful completion of inspections and tests.

7. Define how final product release will be tied to the satisfactory completion of all specified processing, and receiving and in-process inspections and to the acceptability of required documentation and data.

8. Define who is responsible for documenting nonconfomities. Reference could be made to the related procedure for Control of Nonconforming Product.

9. Identify which forms and records are required for complete implementation of this portion of the quality management system.

10. Define the method and responsibility for initial filing and tracking of active inspection and test records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Inspection and Testing procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.11 FOLLOWS)

2.11 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

Element 4.11 of ISO 9001 defines the requirements each enterprise must address for the selection, control, calibration and maintenance of inspection, measurement and test equipment.

Intent

Actively managing the selection, calibration, use and maintenance of inspection, measuring and test equipment will assure that measurement uncertainty is known and is consistent with the measurement capability required for effective process control and product verification.

Benefit

Quantifying, minimizing and controlling measurement uncertainty will substantially reduce the risk of accepting nonconforming product or inadvertently rejecting good product.

Interpretation

The ISO 9001 standard defines the requirements that must be addressed when using inspection, measuring and test equipment:

1. Each enterprise must establish and maintain documented procedures defining their processes for selection, control, calibration and maintenance of all inspection, measuring and test equipment (including test software) that is used to demonstrate conformance of products to specified requirements. Detailed work instructions for specific calibration and maintenance activities may also be needed.

   The selection, control, calibration and maintenance of other inspection, measuring and test equipment that may affect quality, but is not used to demonstrate product conformance, need not be governed by documented procedures. However, they must be selected, controlled, calibrated and maintained in accordance with all other requirements of ISO 9001, element 4.11.

   Measurement equipment not used for product verification might include gauges and instruments used for product development testing, set-up or maintenance of process equipment, and monitoring of process parameters.

2. The measurements to be made during design, development, production, installation or servicing must be identified. Such measurements would include those necessary to effectively monitor and control processes, and to verify product conformance to requirements.

Identification of these measurements could be accomplished as part of the quality planning process (ISO 9001, element 4.2.3) that leads to the development of test and inspection procedures.

3. The required accuracy and precision for each measurement identified above must be defined. Only inspection, measuring, and test equipment that is fully capable of meeting those accuracy and precision requirements must be selected for use. Standardized data sheets can be used to perform accuracy and precision studies to confirm that measurement capability matches requirements.

4. Specific inspection, measurement and test equipment, whose use can affect product quality, must be identified. This could be accomplished using a database referenced in documented procedures or quality planning.

   These gauges and instruments must be calibrated and adjusted at prescribed intervals or prior to use, as appropriate:

   - Calibration standards that are certified as traceable to the National Institute of Standards and Technology must be used.
   - Where NIST traceable standards do not exist, the means of calibration must be documented. This could be done in the Quality Plan (ISO 9000, element 4.2.3) for the applicable product, project or contract.

5. Inspection, measuring and test equipment that cannot be calibrated, but is used to verify product conformance, must be shown to be capable of verifying product acceptability:

   - Capability must be demonstrated before release for use and must be rechecked at prescribed intervals
   - The type and frequency of such capability checks must be defined.
   - Records of these capability checks must be maintained in accordance with ISO 9001, element 4.16.

   Typical articles that cannot be calibrated might include photographs or product samples that are used as workmanship standards, or the software needed to operate test or inspection equipment or analyze measurement input and convert it to an output display.

6. The calibration process must be defined — the documented procedure contained in or referenced in the enterprise's Quality Manual could be used. The calibration process must include the following elements:

   - The specific identity and location of each piece of inspection, measurement, and test equipment that requires calibration must be defined. The database described above could be used.
   - The prescribed calibration frequency and method of calibration must be defined. The same database might be used.
   - The limits within which gauges and instruments may be adjusted, without being declared out of calibration, must be defined.

When the above limits are exceeded, the validity of previous inspection and test results must be assessed and documented. One method would be to document, review and disposition the affected product in the same manner as nonconforming product (ISO 9001, element 4.13).

- Records of calibrations must be maintained in accordance with ISO 9001, element 4.16.
- The calibration status of individual pieces of inspection, measurement, and test equipment must be identified:
  - The calibration due date could be displayed on a label affixed to the Inspection, measurement and test device.
  - Gauges or instruments that are not being calibrated because their use doesn't affect quality could display a "Not Calibrated" label so that inappropriate use is minimized.

7. Environmental conditions must be provided that are suitable for both the calibration and use of inspection, measurement, and test equipment. Temperature, humidity and cleanliness may all require varying levels of control in the areas where both calibration and instrument usage occur, in order to ensure measurement accuracy and precision.

8. The accuracy, precision and resulting fitness for use of inspection, measurement, and test equipment must be protected from inadvertent deterioration by implementing appropriate controls on handling, preservation and storage.

   These methods could be defined in the enterprise's documented procedure for control of inspection, measurement and test equipment or in their handling, storage and packaging procedure.

9. The means of preventing unauthorized adjustments to inspection, measurement, and test equipment must be defined. Comparative standards used for product acceptance and test software must also be protected. Limited access inspection rooms, cabinets and tool cases or tamper-evident seals could be used.

10. If required by the customer, technical data pertaining to the functional adequacy of the enterprise's gauges and instruments must be made available. Such data might include capability studies of measurement precision and accuracy, gauge calibration reports and certifications of calibration standards.

Additional guidance is available in ISO 10012-1 (see Bibliography).

Implementation And Assessment

The enterprise's procedures for selection, control, calibration and maintenance of inspection, measurement and test equipment must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Define the inspection, measurement and test equipment and software that will be controlled under this procedure.

2. Define how the product and process measurements required during design, development, production, installation and servicing will be identified and documented, and who is responsible.

3. Define how the necessary measurement capability will be determined, how measurement equipment will be selected against those criteria, and identify who is responsible.

4. Define the calibration process, including methods for inspection, measurement and test equipment tracking and recall, identification of calibration standards and recall periods. Define permissible calibration tolerances and requirements for calibration environments. Identify who is responsible for establishing these requirements and who is responsible for performing calibrations.

5. Define the method for indicating calibration status at the point of inspection, measurement and test equipment use.

6. Identify the national or international standards against which calibration is verified and identify who is responsible for the maintenance of standards and their documentation.

7. Define how the validity of product acceptance results will be evaluated if inspection, measurement, or test equipment is found to be out of tolerance during calibration.

8. Identify how use, maintenance, and calibration requirements will be communicated to the functions affected. Reference could be made to the related procedure for Inspection and Testing.

9. Define the methods used to prevent unauthorized adjustment of inspection, measurement, and test equipment.

10. Define the handling, preservation and storage practices needed to preserve accuracy and prevent damage and loss of use.

11. Identify which forms and records are required for complete implementation of this portion of the quality management system.

12. Define the method and responsibility for initial filing and tracking of calibration records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Control of Inspection, Measuring and Test Equipment procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.12 FOLLOWS)

2.12 INSPECTION AND TEST STATUS

Element 4.12 of ISO 9001 defines the requirements an enterprise must address to adequately identify each product's inspection and test acceptance or rejection status.

Intent

To preclude the inadvertent use of product that has not successfully completed all prescribed processing and verification steps, each item's inspection and test status should be readily identifiable.

Benefit

The avoidable delays, extra costs and customer dissatisfaction resulting from inappropriate release of product for processing, assembly or use will be minimized when product acceptance status is clearly identified.

Interpretation

The standard requires each enterprise to define how inspection and test status will be identified in its quality plan or in documented procedures:

1. The status of product conformance or nonconformance to specified inspection and test requirements must be identified. It should be readily evident whether or not specific units or batches have completed the necessary inspections and tests. Once an inspection or test is completed, it should also be evident whether the product has passed or failed. Tags, stamps, labels and processing travelers could be used.

2. The identification of inspection and test acceptance status must be maintained during all phases of production, installation and servicing.

3. Only product that has successfully passed all specified inspections and tests, or has been authorized for use in accordance with documented procedures for control of nonconforming product (ISO 9001, element 4.13) can be released for use.

Implementation And Assessment

The enterprise's procedures for identifying product acceptance status must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Define any marking or tagging methods and the type of documentation that will be used to indicate whether inspections and tests have been completed, and the resulting accept / reject status.

2. Define who is responsible for identifying and maintaining the identification of accept / reject status of inspected and tested product.

3. Identify which forms and records are required for complete implementation of this portion of the quality management system.

(SECTION 2.13 FOLLOWS)

2.13 CONTROL OF NONCONFORMING PRODUCT

Element 4.13 of ISO 9001 defines the requirements each enterprise must address to adequately control nonconforming products.

Intent

The systematic management of nonconforming product should prevent its unintended use.

Benefit

To minimize the budget impact and customer dissatisfaction from products that fail to meet requirements, it is essential that known nonconforming product be controlled to preclude its inadvertent use.

The systematic documentation and evaluation of nonconforming product also provides a basis for improvement of supplier and internal processes.

Interpretation

The standard requires each enterprise to establish and maintain documented procedures that preclude the unintended use of nonconforming product:

1. Nonconforming product includes such items as raw materials, procured articles, and parts, components or assemblies that do not meet specified requirements. Product that fails to function as intended is typically treated as nonconforming.

2. Nonconforming product must be identified. Reject tags, stamps, labels or other suitable means can be used.

3. Nonconforming product must be documented. Nonconformance reports are often used to fully identify the product and its condition, and to facilitate and record the evaluation and disposition of the product.

4. To the maximum extent practical, physical segregation of nonconforming product from acceptable product is required. Limited access storage rooms, locked cabinets or roped off areas for large articles could be used.

5. The individual or group that is authorized to evaluate and disposition the nonconforming product for use, rework, repair, scrap or replacement must be defined. This function is sometimes delegated to a Material Review Board comprised of members who can knowledgeably address product design margins and functionality, safety and necessary supplier or internal corrective actions.

6. Nonconforming product must be evaluated in accordance with documented procedures. Such procedures might:
   - ◆ Define when customer involvement is required.
   - ◆ Provide guidelines for authorizing repair, re-grading or use-as-is dispositions.
   - ◆ Define when failure analysis must be undertaken.
   - ● Identify when the design rationale for a disposition must be documented.

7. The identified nonconformance, and the resulting evaluation and disposition must be communicated to all concerned functions. This might be accomplished by distribution of the Nonconformance Report.

   Concerned functions might include those responsible for product design or for process design, maintenance and operation; the purchasing function or supplier quality function; the enterprise's supplier or customer, or perhaps regulatory agencies.

8. If required, the customer or their representative must approve the proposed use of nonconforming product, or its repair to a functional but still nonconforming condition:
   - ◆ A record of such customer concessions must be kept, clearly describing the condition that was accepted and describing the nature of any repairs.
   - ◆ These records must be managed in accordance with ISO 9001, element 4.16.

9. Nonconforming product that has been reworked to a conforming condition, or has been repaired to a functional, but still nonconforming condition must be re-inspected in accordance with documented procedures. These documented procedures might include standard inspection instructions or special inspection and acceptance requirements defined by an authorized Material Review Board.

10. The management and closure of corrective actions resulting from evaluation of nonconforming product could be addressed in the documented procedure for control of nonconforming product or in the related corrective action procedures required by ISO 9001, element 4.14.

Implementation And Assessment

The enterprise's procedures for management of nonconforming product must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Define the forms to be used for documenting nonconformances and how nonconformances will be evaluated and dispositioned.

2. Define who is authorized to document nonconformances.

3. Define the required methods for identification and segregation of nonconforming product.

4. Identify how affected functions will be notified of nonconformances.

5. Define who is authorized to evaluate the nonconformance and to specify disposition of the product. For nonconformance closure, reference should be made to the enterprise's related procedure for Corrective and Preventive Action.

6. If required, define how customers will be notified of nonconformances and how their approval for use or repair will be obtained.

7. Define how repaired, re-graded and reworked product will be verified as conforming to applicable requirements. Reference could be made to the related procedure for Inspection and Testing.

8. Identify which forms and records are required for complete implementation of this portion of the quality management system.

9. Define the method and responsibility for initial filing and tracking of non-conformance documents, including customer concessions. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Nonconforming Product Control procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.14 FOLLOWS)

2.14 CORRECTIVE AND PREVENTIVE ACTION

Element 4.14 of ISO 9001 specifies the major elements that must be present in each enterprise's processes for corrective action and for preventive action.

Intent

Corrective action processes strive to eliminate the root causes of existing product and service nonconformities. Preventive action processes seek to identify possible nonconformities before they occur and eliminate their root causes.

Benefit

Actively managed corrective and preventive action processes will systematically improve process performance, resulting in fewer product and service problems that affect customers and require unbudgeted resources to evaluate and correct.

A sustained effort to prevent nonconformities from occurring will improve first time conformance and justify reduced inspection and audit expenditures for nonconformance detection.

Interpretation

The standard requires each enterprise to establish and maintain documented procedures for implementing both corrective and preventive action processes:

1. Any operating changes resulting from the corrective and preventive action processes must be fully implemented and the applicable documented procedures must be revised. Corrective and preventive action processes that permanently capture upgraded methods are the basis for long term continuous improvement.

2. The extent of the preventive or corrective actions taken to eliminate future or current non-conformities should be appropriate for the magnitude of the problem and the resulting risk.

3. Information on preventive and corrective actions must be provided to management for inclusion in their regular review of the effective functioning of the enterprise's quality system (ISO 9001, element 4.1.3).

The documented procedure for corrective action must include:

1. An effective process for handling customer complaints and reports of product nonconformance.

2. The analysis of product, process and quality system nonconformities to identify and document their causes:
   - Such nonconformities might include:
     - Findings from internal audits, customer or third party audits, audits by regulatory bodies, and the enterprise's audits of their supplier's quality systems.
     - Action items from executive management's reviews of quality system effectiveness.
     - Rejections from source, receiving, in-process and final inspections and tests.
     - Current customer complaints and field failures.
   - Analytical techniques like "fish bone" cause and effect charts could be used to identify both the immediate causes of nonconformance and their root causes.
   - The results of the cause and effect investigation must be recorded in accordance with the quality records provisions of ISO 9001, element 4.16. A simple Corrective Action Request (CAR) form could be used.

3. The determination of the corrective actions needed to permanently eliminate the identified root causes. The above mentioned CAR could be used to document the specific actions necessary to eliminate the identified root causes.

4. Verification that the specified corrective action has been taken, and verification that it has actually eliminated subsequent nonconformance. The period required to confirm no further recurrence should be significantly longer than the average frequency of past occurrences. Closure data could be recorded on the Corrective Action Request form.

The documented procedure for preventive action must include:

1. The analysis of appropriate operating data to detect emerging trends and assignable causes that may result in future nonconformities. Such data sources could include:
   - Equipment operation logs and process control charts.
   - Records of requirements reviews and design reviews.
   - Records of design changes.
   - Supplier performance records.
   - Process cycle time and process capability metrics.
   - Process yield metrics and defect rankings.
   - Internal and external audit reports.
   - Customer granted concessions.
   - Service records and field failure records.

Cost of quality data might also be reviewed in order to optimize the level of defect prevention effort versus conformance assessment effort and defect correction effort (see Section 2.21 of this guide).

2. Determination of the actions needed to deal with potential problem areas that warrant preventive action.

3. The implementation of the appropriate preventive action and the verification that the preventive action has been effective in eliminating the problem area. One measure of effectiveness might come from monitoring the data that highlighted the original problem for a significantly longer period than the previous frequency of occurrence.

Implementation And Assessment

The enterprise's procedures for corrective action and preventive action must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Define how requests for corrective actions and requests for preventive actions will be documented, including identification of any forms to be used.

2. Identify which organizational functions are expected to generate corrective action requests to remedy nonconformities.

3. Identify which organizational functions are expected to generate preventive action requests to eliminate the causes of potential nonconformities. Also identify the typical sources of information and data that should be analyzed to detect possible problems and emerging adverse trends.

4. Define how current and potential nonconformities will be analyzed to determine their root cause. Also identify who is responsible for undertaking the investigation and recording the results.

5. Identify who is authorized to review corrective action requests and preventive action requests to assure that they:
   - Will eliminate the root cause of the problem.
   - Are appropriate to the magnitude and impact of the problem.

6. Define how the implementation of corrective actions and preventive actions will be verified. Also define how to confirm that the implemented action has actually eliminated the original problem.

7. Define how relevant corrective action and preventive action information will be communicated for use in executive management's periodic reviews of quality

system effectiveness. Also identify who is responsible for communicating this information.

8. Identify how changes resulting from the corrective action process and from the preventive action process will be captured in revisions to documented operating procedures and who is responsible for initiating such revisions.

9. Identify which forms and records are required for complete implementation of this portion of the quality management system.

10. Define the methods and responsibility for the initial preparation, filing, and tracking of corrective action records and preventive action records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Corrective and Preventive Action procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.15 FOLLOWS)

2.15 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

Element 4.15 of ISO 9001 specifies the requirements that each enterprise's processes for product handling, storage, packaging, preservation and delivery must meet.

Intent

Clearly defined requirements and processes for handling, storage, packaging, preservation and delivery will significantly reduce inadvertent damage, deterioration or unavailability of necessary articles at all stages of processing.

Benefit

Product that is damaged or is allowed to deteriorate during receipt, processing, storage or delivery will cause unpredictable extra costs, schedule slippage and customer dissatisfaction that could be avoided by designing and implementing systematic product integrity controls.

Interpretation

The standard requires each enterprise to establish and maintain documented procedures for handling, storage, packaging, preservation and delivery:

1. Handling methods that prevent product degradation must be developed and implemented:
   - ◆ Controls should be implemented throughout the enterprise's operations, from receiving until responsibility for the product passes to another party.
   - ◆ Training, such as electrostatic discharge prevention or clean room practices, could be provided.
   - ◆ The design of workstations, fixtures, tools, gauges, containers and handling equipment can be optimized to significantly reduce handling damage.
2. Designated storage areas must be used to prevent damage or deterioration pending in-process use or delivery. Methods for authorizing receipt to and removal from such stock areas must be defined:
   - ◆ Secure cabinets, rooms or fenced cribs could be used.
   - ◆ For just-in-time or pull production systems, specifically designated fixtures, carousels, racks, dollies or bins might be used.
   - ◆ Stocking and withdrawal controls might include:
     - Receiving Inspection's "release for stocking" stamp.

- Withdrawal from raw stock only with build travelers issued by Production Control.
- In-process stocking or withdrawal based on authorized signatures on process travelers indicating completion of necessary operations.
- Removal from finished stores only with the certification group's shipment release stamp.

3. To detect possible deterioration, regular assessments of stored product must be made:
   - ◆ Shelf life date stamps or tags can be employed for limited life items.
   - ◆ Regularly scheduled full or cycle inventories can be performed to assess product integrity at the same time that the accuracy of inventory quantity and identity is assessed.
   - ◆ First-in-first-out stocking systems could be used to minimize the potential for product deterioration.

4. Use of packaging, packing and marking processes and materials must be specified and controlled:
   - ◆ For procured articles, authorized marking and packaging materials could be specified in product drawings or referenced packaging specifications.
   - ◆ The internal application of approved marking, packaging and packing materials, methods and containers could be defined in standard packing procedures, processing travelers or authorized checklists of selectable packaging requirements.

5. To preserve integrity and avoid unintended commingling while product is in the enterprise's control, appropriate methods, materials and environments must be specified and implemented. When contractually specified, the enterprise's responsibility could extend through delivery, installation and commissioning.

   Data sheets, travelers, work instructions, installation and service manuals could be used to define and communicate intended practices.

Implementation And Assessment

The enterprise's procedures for handling, storage, packaging, preservation and delivery of product must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Define what types of training are necessary to assure that personnel are proficient in correct handling methods. Reference could be made to the related procedure for Training.

2. Define how the design and maintenance of workstation fixtures, tools, gauges and storage or transfer devices will be developed and controlled to minimize handling damage. Also identify who is responsible for such workstation design and maintenance activities.

3. Identify how and where product must be stored pending use or delivery. Also define how receipt into storage and dispatch from storage will be authorized and who is responsible for these authorizations.

4. Define how stock will be managed to minimize deterioration and when the condition of stored product will be assessed to detect deterioration, including who is responsible for such assessments.

5. Identify how product marking, packaging and packing materials and methods will be defined, communicated and implemented. Also define who is responsible.

6. Define any materials and environments that will be required to preserve product integrity during processing, delivery or installation and who is responsible for their implementation.

7. Identify which forms and records are required for complete implementation of this portion of the quality management system.

8. Define the method and responsibility for the initial filing and tracking of active records that document conformance to specified handling, storage and packaging requirements. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Handling, Storage and Packaging procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.16 FOLLOWS)

2.16 CONTROL OF QUALITY RECORDS

Element 4.16 of the ISO 9001 standard defines the requirements for management of quality records.

Intent

Quality records are the basis for the acceptance of product, and for the measurement and improvement of operating processes and the quality management system.

Benefit

Quality records are a major source of data needed to efficiently plan, budget and manage functional organizations, and analyze and improve the effectiveness of their processes and the enterprise's quality system.

Quality records also provide management, suppliers and customers with tangible evidence of conformance to their requirements.

Interpretation

The standard requires each enterprise to establish and maintain documented procedures for the identification, collection, indexing, access, filing, storage, maintenance and eventual disposal of quality records.

Quality records are those documents or data that provide evidence of:

- The effective operation of the organization's quality management system.
- The capability of key personnel, processes or suppliers.
- The controlled operation of processes that affect quality.
- Product conformance to specified requirements.

Such quality records might include:

- Design review meeting minutes.
- Training records.
- Calibration reports.
- Customer complaints.
- Design validation test results.
- Inspection and test reports.
- Completed processing travelers.
- Corrective action requests.
- Management review meeting minutes.
- Prevention, detection and correction costs.
- Design verification calculations.
- Records of customer supplied product.
- Internal audit reports.
- Completed certification examinations.

- Supplier audit results.
- Supplier performance data.
- Product nonconformance reports.
- Control charts from special processes.
- Requirements review meeting minutes.
- Approved customer concessions.

Data provided by suppliers for purchased articles that affect the quality of final products may also need to be managed as quality records.

The standard's specific requirements include:

1. All quality records must be legible.

2. Records must be stored and retained so as to be readily retrievable. Records would probably be considered readily retrievable if they could be accessed in time to avoid a disruption to operations. Using another approach - retrieval within 24 hours is often used as a rule of thumb.

3. The storage environment for quality records must preclude loss, damage or deterioration. Hardcopy, microfilm and electronic records may have differing needs for temperature, humidity and contamination control and fire or electromagnetic field protection.

4. The minimum retention period, and the method and authority for eventual disposal of the records, must be defined and documented. When required by the customer, quality records must be available for customer evaluation for an agreed period. When not contractually defined, retention periods are often based on regulatory requirements, liability or product lifetime considerations. Retention periods of 5 to 7 years are frequently encountered.

Implementation And Assessment

The enterprise's procedures for identification, collection, indexing, access, filing, storage, maintenance and eventual disposition of quality records must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Identify which types of data will be treated as quality records.

2. Identify who is responsible for interpreting the criteria that define which data are quality records.

3. Define how quality records will be initially accumulated, indexed, filed and stored while they are considered active records requiring regular use.

   NOTE: This might be done in a single Quality Records procedure, or in the individual procedures defining each activity that generates or receives quality records.

4. Also define how such quality records will be stored, accessed and eventually dispositioned when they are considered inactive records subject only to infrequent use.

5. Identify how legibility will be confirmed and who is responsible.

6. Define guidelines for acceptable record retrievability leadtime.

7. Define the criteria for environmental conditions for records storage and who is responsible for their implementation and maintenance.

8. Identify the conditions under which records will be made available to customers.

9. Define the required quality record retention period and the method of eventual disposal.

10. Identify who has the authority to initiate disposal of quality records.

11. Identify which forms and records are required for complete implementation of this portion of the quality management system.

(SECTION 2.17 FOLLOWS)

2.17 INTERNAL QUALITY AUDITS

Element 4.17 of ISO 9001 defines the requirements for each enterprise's internal quality audit process.

Intent

Internal quality audits provide organizations with a continuous review of the effectiveness of their quality management system. Internal quality audits also characterize the level of day-to-day compliance to the enterprise's approved process and product requirements.

Benefit

Opportunities for the continuous improvement of operating processes will be systematically identified through regularly scheduled internal audits of the enterprise's quality management system.

Internal audits also help to identify areas of degraded practices or obsolete procedures that can result in costly product nonconformities and customer dissatisfaction.

Interpretation

The standard requires each enterprise to establish and maintain documented procedures for planning and implementing internal quality audits:

1. Internal audits must verify the effective operation of the quality system and whether quality related activities and associated results comply with specified requirements. For each operational area, audit checklists could be developed based on ISO 9001, this guide and the organization's documented quality plans and operating procedures.

2. Audits should be scheduled based on the status and importance of the activity being assessed. Areas with recurring process, product or procedure problems warrant more frequent and more comprehensive audits than low risk or problem free areas where less frequent audits of a few key elements may be sufficient.

3. The selected auditors must not have a direct responsibility for the operations being audited. For example, Human Resources personnel might be precluded from participating in audits of the training process, but they could effectively audit in the area of management responsibility (ISO 9001, element 4.1).

4. Results of internal quality audits must be:

   - Recorded, and the records managed in accordance with the requirements of ISO 9001, element 4.16.

- Coordinated with personnel responsible for the areas being audited. Since internal audits are improvement oriented, area personnel could:
  - Assist auditors in their development of audit checklists.
  - Provide on-scene assistance to the auditor in scheduling personnel availability, explaining operating methods and obtaining relevant documents and records.
  - Provide real-time validation or correction of the auditor's observations.
  - Assist the auditor in analyzing problem areas for root cause and in defining appropriate corrective actions.

  When the exit interview occurs, there would already be complete understanding by all parties.

5. Results of internal quality audits should also be part of executive management's review of the effectiveness of the quality management system, in accordance with ISO 9001, element 4.1.3.

6. Management personnel responsible for the area being assessed must take timely and effective action to correct any identified deficiencies.

   Providing trend charts on the age of open corrective action requests for executive management's review (ISO 9001, element 4.1.3) could provide the necessary visibility to assure that resources are prioritized for timely process improvement.

7. Follow-up audits must be conducted to verify and document that corrective actions have been implemented, and that they have been effective in eliminating the original problem. These records of follow-up audits must be managed in accordance with ISO 9001, element 4.16.

Implementation And Assessment

The enterprise's procedures for managing and conducting internal quality audits must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Define how the frequency, depth and schedule for internal audits will be established.

2. Identify who is responsible for developing and communicating overall internal audit schedules to affected groups and how such communications will be made.

3. Identify who will perform the internal audits, or how the auditors will be selected to assure their independence, and who is responsible for their selection.

4. Define who is responsible for establishing and communicating the membership of each audit team and its agenda and specific schedule.

5. Define the responsibility of area personnel to participate in the pre-audit, audit and post-audit process.

6. Identify in what form audit results will be documented, and who is authorized to communicate them to the responsible management. Reference could be made to the related procedure on Corrective and Preventive Action.

7. Define how open audit findings will be tracked and their status reported to management to assure timely closure. Also identify who is responsible for tracking and reporting.

8. Define who is responsible for scheduling and conducting follow-up audits to assure that corrective actions have been taken and that they have actually eliminated the observed problem.

9. Identify who is authorized to close-out corrective actions from internal audits and how close-out will be documented.

10. Identify which forms and records are required for complete implementation of this portion of the quality management system.

11. Define the method and responsibility for initial filing and tracking of active internal audit records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Internal Quality Audit procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.18 FOLLOWS)

2.18 TRAINING

Element 4.18 of ISO 9001 defines the requirements for managing the identification and delivery of necessary training.

Intent

Systematically identifying, planning and providing appropriate training to personnel whose work affects quality will ensure that they possess the necessary knowledge, skills and proficiency to consistently meet requirements.

Benefit

The unbudgeted time and effort needed to correct errors and omissions will be reduced when personnel are systematically provided with the training necessary to become fully proficient in their job. Fewer errors and omissions will also result in increased customer satisfaction, particularly in service oriented processes where personnel have frequent customer contact.

Interpretation

The standard requires each enterprise to establish and maintain documented procedures for managing the identification and delivery of quality-critical training:

1. The training needs of all personnel whose work affects quality must be defined. This might include executive management, supervision, professional and hourly personnel.

   Some training may be specified by regulatory bodies or be defined in contracts. However, most training will probably be internally driven - based on the enterprise's need to satisfy customer expectations for high quality, timely delivery and low cost.

2. Personnel must be qualified for their specific assigned tasks by having or receiving the required training, education and experience:

   - Training data sheets could be developed, defining the required knowledge base and proficiency level for each job classification. Then, in-house or external training sources could be identified for each type of required training.
     - The need for special skills for each product, project or contract could first be identified in the enterprise's quality planning documents (ISO 9001, element 4.2.3), and entered in the appropriate training data sheets.
     - The need for certification of personnel who operate special processes (ISO 9001 element 4.9), including the need for proficiency testing, could

first be identified in the enterprise's quality planning documents (ISO 9001, element 4.2.3), and entered in the appropriate training data sheets.

- Each employee's unique experience and skills could be recorded on the appropriate data sheet for their job classification. With a well designed data sheet, any gaps between actual and required skills would be automatically highlighted.

3. Each organization must systematically plan, budget and ensure the delivery of the necessary training.

   Completion of the training data sheet suggested above would identify specific training needs, and could also act as the work sheet for costing and scheduling the training - thus becoming that individual's training plan.

4. Records of personnel training must be maintained in accordance with ISO 9000, element 4.16.

   Recording the completion of training on the above mentioned data sheet could produce a comprehensive record of the entire training identification, planning, budgeting and delivery cycle.

Implementation And Assessment

The enterprise's procedures for training must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Define how the tasks, activities and functions that affect quality will be identified for training purposes and who is responsible for their definition.

2. Define how the specific training, education and experience requirements for each identified task will be determined, how they will be documented and who is responsible.

3. For personnel who must be pre-qualified to perform special processes in accordance with ISO 9001 element 4.9, define how such pre-qualification requirements will be established, including the need for any proficiency testing.

4. Define who is responsible for establishing such pre-qualification requirements.

5. Define how employee experience and skills will be compared to the previously defined requirements for their position. Also identify who is responsible for performing this comparison.

6. Identify who is responsible for assuring that training budgets and schedules are developed.

7. Identify who is responsible for assuring that the planned and budgeted training is delivered.

8. Identify which forms and records are required for complete implementation of this portion of the quality management system.

9. Define the method and responsibility for initial filing and tracking of training records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Training procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.19 FOLLOWS)

2.19 SERVICING

Element 4.19 of ISO 9001 defines the requirements for managing servicing activities.

Intent

Defining, documenting and actively managing servicing processes should result in optimum product performance that meets customer expectations.

Benefit

The systematic design and delivery of product servicing will maximize the probability that servicing requirements will be met and that product quality will not be inadvertently degraded by servicing errors or omissions.

Preventing servicing errors and omissions will reduce unexpected cost and schedule impacts to the enterprise and their customers. The loss of product use by the customer will also be minimized.

Interpretation

Where product servicing is a specified requirement, the standard requires each enterprise to establish and maintain documented procedures for their servicing processes. Product servicing might occur during or after delivery, installation or commissioning. Such documented servicing procedures should define:

1. How the product servicing is to be performed. The intended servicing methods, tools, equipment, materials and product operating parameters could be documented.

2. How conformance to requirements will be verified. Any necessary inspection and testing methods, gauges, instruments, equipment and acceptance criteria could be defined.

3. How the completion of servicing, and its conformance to specified requirements, will be reported. Checklists or work orders completed by the service person and countersigned by the user might be used.

Implementation And Assessment

The enterprise's procedures for servicing must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures should:

1. Identify which products, projects or contracts require servicing and documented servicing procedures. Also identify who is responsible for making these determinations.

2. Define how the methods, technical specifications, tools, equipment, materials, fixtures and personnel qualifications required to perform the servicing will be developed, documented and approved.

3. Identify how any inspection or testing methods, acceptance criteria, gauges, instruments or equipment required to verify conformance to requirements will be developed, documented and approved.

4. Define who is responsible for developing and documenting such servicing and verification procedures.

5. Identify how servicing schedules will be developed and communicated to affected parties, and who is responsible.

6. Identify how the field availability of the specified tools, equipment, fixtures, spares, calibrated gauges and instruments, and qualified personnel will be assured, and who is responsible for such planning and deployment.

7. Define how the completion of servicing and the verification of conformance to requirements will be reported, to whom it must be reported and who is responsible for such reporting.

8. Identify which forms and records are required for complete implementation of this portion of the quality management system.

9. Define the method and responsibility for initial filing and tracking of servicing verification records. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Servicing procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.20 FOLLOWS)

2.20 STATISTICAL TECHNIQUES

Element 4.20 of ISO 9001 defines the requirements for identification and application of appropriate statistical techniques to the enterprise's processes and products.

Intent

When properly applied, statistical techniques are powerful tools for the analysis, management and improvement of product designs and operating processes.

Benefit

Simple graphical tools, commercially available software and advanced mathematical techniques help characterize and improve process performance leading to more frequent conformance to the enterprise's requirements and reduced operating costs.

Statistical techniques are used to analyze and improve the safety and reliability of product designs. They can also be used as preventive action tools to evaluate operating records and identify emerging trends.

Statistical sampling plans reduce the leadtime and resources required to verify product conformance to specified requirements.

Interpretation

The standard requires each enterprise to identify necessary applications for statistical techniques and establish and maintain documented procedures for their use:

1. Work processes must be evaluated to identify beneficial uses for specific statistical techniques. Statistical techniques might be used to:
   - ◆ Evaluate and improve the reliability of new product designs.
   - ◆ Analyze, improve and control the unintended variability of key processes.
   - ◆ Predict or analyze field failures.
   - ◆ Conduct valid customer surveys using cost effective sampling.
   - ◆ Predict product performance based on limited prototype testing.
   - ◆ Uncover cause and effect relationships.
   - ◆ Analyze supplier performance and highlight adverse trends.
   - ◆ Release new processes and products for production based on limited qualification data.
   - ◆ Analyze customer complaint data.

- Perform lot sampling to verify product conformance to requirements.
- Characterize the accuracy and precision of gauges and instruments.
- Analyze operating data to uncover emerging trends and initiate preventive actions before significant problems arise.

The areas identified for application of statistical techniques could be defined in the Quality Plan for each product, project or contract (ISO 9001, element 4.2.3).

2. The means of deploying and controlling the identified statistical techniques must be documented. Requirements for applying statistical techniques could be defined in applicable operating procedures or work instructions.

Implementation And Assessment

The enterprise's procedures for application of statistical techniques must be documented. Once adequately documented each element of these procedures must be fully implemented, as evidenced by direct observation of activities, records, or data.

The documented procedures or work instructions should:

1. Define which statistical tools should be used for each application. This might include:
   - The intended frequency of use.
   - Requirements for the type and quantity of data needed to assure valid analytical results.
   - Identification of the appropriate analysis and reporting forms or software packages.
2. Identify who is responsible for application of the statistical tools, and for analysis and reporting of the results. Also identify who is responsible for initiating any necessary preventive or corrective actions based on the results.
3. Identify which forms and records are required for complete implementation of this portion of the quality management system.
4. Define the method and responsibility for initial filing and tracking of statistical records where such data is used to assess conformance to requirements, or to assess the effectiveness of the organization's quality system. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Statistical Techniques procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(SECTION 2.21 FOLLOWS)

2.21 QUALITY COSTS

Element 6 of ISO 9004-1 provides guidelines for measuring the effectiveness of an enterprise's quality management system in financial terms. ISO 9004-1 is a guidance standard, intended for in-house application rather than for contractual compliance. Accordingly, Quality Costs are not discussed in ISO 9001, which is intended to be a conformance standard.

Intent

Quantifying all of the costs to conform to requirements allows quality system effectiveness to be measured in the same way as other key operating parameters that warrant regular management attention.

Benefit

Measuring and reporting quality costs permits the optimum allocation of resources between nonconformance prevention, detection and correction activities.

Analysis of quality costs is a useful tool for initiating those process improvement projects that will produce the largest benefit. The consistent application of adequate prevention resources will minimize errors and omissions - reducing the need for resource intensive inspections, tests and audits. And with fewer nonconformities to detect, fewer will reach the customer - resulting in increased satisfaction and decreased complaint costs.

Interpretation

The standard proposes that each enterprise establish and maintain procedures for the measurement, accumulation, analysis and reporting of all costs incurred to meet requirements:

1. Costs to prevent errors and defects might include:
   - Personnel training and certification.
   - Creation of design development plans and project quality plans.
   - Requirements development and review activities.
   - Design of workstations and fixtures to preclude product damage.
   - Process improvement team meetings.
   - Scheduled maintenance.
   - Customer surveys and focus groups.
   - Defining and documenting operating procedures.

2. Costs to assess conformance to requirements might include:
   - Design review meetings.
   - Design verification analyses and testing.
   - Validation of designs for user applications.
   - Gauge or process capability studies.
   - Management reviews of quality system effectiveness.
   - Post-drafting check of engineering drawings.
   - Hardware and software product inspections and tests.
   - Proof reading of user manuals and other documentation products.
   - Internal or supplier quality audits.
   - Support for customer or third party quality audits.

3. Costs to correct errors and defects might include:
   - Hardware, software and documentation rework and reinspection.
   - Material Review Board meetings.
   - Scrap (material plus labor).
   - Expediting fees, unplanned overtime and premium transportation.
   - Costs of responding to regulatory agency citations and customer or internal audit findings.
   - Travel and living costs to address field problems.
   - Costs to document, evaluate, approve and implement design changes.

The total of all costs to conform to requirements, and the ratio of prevention costs to assessment costs plus correction costs, are excellent measures of the effectiveness of the quality management system and could be reported to executive management for inclusion in their periodic reviews (ISO 9001, element 4.1.3).

Graphical trend charting of total quality costs and the prevention ratio can be a major tool in implementing the preventive action requirements of ISO 9001, element 4.14.3. A rolling trend of the most recent 10 or 15 reporting periods might be used.

To be an effective tool for managing quality systems, quality cost reporting may not require the same frequency and accuracy as traditional cost accounting systems. A periodic "snap shot" that includes both cost accumulation and cost estimation elements may be sufficient for management to make fact based resource allocation decisions.

Implementation And Assessment

The enterprise's procedures for recording, accumulating, analyzing and reporting the costs of conformance to requirements should:

1. Identify which functions will participate in quality cost reporting.

2. Define the categories and frequency for recording quality costs, including the identification of any necessary cost collection forms.

3. Define how these records of quality costs will be accumulated and who is responsible for their accumulation.

4. Identify who is responsible for the analysis of quality costs and who will generate and distribute the analysis reports.

5. Define how frequently, to whom, and in what form the quality cost analyses will be reported.

6. Identify who is responsible for reviewing quality cost analyses and initiating appropriate preventive or corrective actions. For tracking and closure, reference can be made to the related procedure for Corrective and Preventive Action.

7. Identify which forms and records are required for complete implementation of this portion of the quality management system.

8. Define the method and responsibility for initial filing and tracking of quality cost data. Subsequent record accumulation, maintenance and disposition could be defined in the enterprise's Quality Costs procedure or in related procedures for Quality Records (ISO 9001, element 4.16).

(BIBLIOGRAPHY FOLLOWS)

BIBLIOGRAPHY

In the United States, the most frequently used ISO standards are sponsored by the American National Standards Institute and published by The American Society for Quality Control. They may be purchased from ASQC: (800) 248-1946.

1. **ANSI/ASQC Q9000-1**, *Quality Management and Quality Assurance Standards -- Guidelines for Selection and Use.*

2. **ANSI/ASQC Q9001**, *Quality Systems -- Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.*

3. **ANSI/ASQC Q9002**, *Quality Systems -- Model for Quality Assurance in Production, Installation, and Servicing.*

4. **ANSI/ASQC Q9003**, *Quality Systems -- Model for Quality Assurance in Final Inspection and Test.*

5. **ANSI/ASQC Q9004-1**, *Quality Management and Quality System Elements -- Guidelines.*

6. **ANSI/ASQC Q10011-1**, *Guidelines for Auditing Quality Systems -- Auditing.*

7. **ANSI/ASQC Q10011-2**, *Guidelines for Auditing Quality Systems -- Qualification Criteria for Quality Systems Auditors.*

8. **ANSI/ASQC Q10011-3**, *Guidelines for Auditing Quality Systems -- Management of Audit Programs.*

Other relevant ISO standards may be purchased from ANSI: (212) 642-4900.

9. **ISO 8402**, *Quality Management and Quality Assurance -- Vocabulary.*

10. **ISO 9000-2**, *Quality Management and Quality Assurance Standards -- Part 2: Generic Guidelines for the Application of ISO 9001, ISO 9002 and ISO 9003.*

11. **ISO 9000-3**, *Quality Management and Quality Assurance Standards -- Part 3: Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software.*

12. **ISO 9004-2**, *Quality Management and Quality System Elements -- Guidelines For Services.*

13. **ISO 9004-3**, *Quality Management and Quality System Elements -- Guidelines For Processed Materials.*

14. **ISO 9004-24**, *Quality Management and Quality System Elements -- Guidelines For Quality Improvement.*

15. **ISO 10012-1**, *Quality Assurance Requirements for Measuring Equipment -- Part 1: Metrological Confirmation System for Measuring Equipment.*

16. **ISO 10013**, *Guidelines For Developing Quality Manuals.*

17. **ISO Handbook 3**, *Statistical Methods*

(END OF DOCUMENT)

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	September 1996	Reference Publication

4. TITLE AND SUBTITLE

ISO 9000 Implementation and Assessment
A Guide to Developing and Evaluating Quality Management Systems

5. FUNDING NUMBERS

UPN323-93-95

6. AUTHOR(S)

Robert J. Navarro and Barry Grimm

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Ames Research Center
Moffett Field, CA 94035-1000

8. PERFORMING ORGANIZATION REPORT NUMBER

A-962836

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

National Aeronautics and Space Administration
Washington, DC 20546-0001

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

NASA RP-1392

11. SUPPLEMENTARY NOTES

Point of Contact: Robert J. Navarro, Ames Research Center, MS 218-7, Moffett Field, CA 94035-1000; (415) 604-5640

12a. DISTRIBUTION/AVAILABILITY STATEMENT

Unclassified — Unlimited
Subject Category 99

12b. DISTRIBUTION CODE

13. ABSTRACT ***(Maximum 200 words)***

The agency has developed this reference publication to aid NASA organizations and their suppliers in the transition to ISO 9000. This guide focuses on the standard's intent, clarifies its requirements, offers implementation examples and highlights interrelated areas. It can assist anyone developing or evaluating NASA or supplier quality management systems.

The ISO 9000 standards contain the basic elements for managing those processes that affect an organization's ability to consistently meet customer requirements. ISO 9000 was developed through the International Organization for Standardization and has been adopted as the U.S. national standard. These standards define a flexible foundation for customer focused process measurement, management and improvement that is the hallmark of world class enterprises.

14. SUBJECT TERMS	15. NUMBER OF PAGES
ISO 9000, Quality management system, Process management standard	75
	16. PRICE CODE: A04

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified		